Characterization of Materials for Shape-memory and Biodegradable Ureteral Stent

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Abstract. Ureteral stent is one of the commonly used instruments in urology, and its clinical efficacy is confirmed. However, there are also a series of complications or deficiencies, including infection after catheterization, formation of stent shell, and secondary endoscopy for tube extraction. The biodegradable ureteral stent can play the same role as the double-J tube, and it will be completely degraded after a certain time. The degradation fragments will be discharged with the urine, and the physiological functions of the ureter will not be affected. At the same time, there is no need to perform a second cystoscope for tube extraction. Therefore, patients do not have to undergo an invasive operation again, so as to alleviate the pain of patients and save time and cost.

1. Introduction

Ureteral stents are one of the most commonly used instruments in urology. Urinary tract, especially after upper urinary tract operation or surgery, the placement of ureteral stents has become a routine procedure in urological surgery. Its main function is to ensure the unobstructed urine drainage and provide a certain degree of support for the ureter. As an auxiliary treatment for urolithiasis, it can relieve various benign and malignant obstructions, promote the recovery of ureter and prevent urinary extravasation[1]. The most common ureteral stent in clinical practice is the double-j catheter (pigtail catheter to prevent ureteral displacement), which was first used by Finney et al in 1978[2]. While achieving good clinical effect, there are also many complications or deficiencies, such as catheter after infection, a leather case formation, lateral lumbar discomfort, abdominal pain and bladder irritation, urine bladder ureter reflux, after catheter forgotten, endoscopic operation secondary tube (such as for children, two tube sedation or general anesthesia, giving patients has brought a series of unwell, influence the patient's quality of life.

2. Degradable Polymer Ureteral Stent

2.1. Polylactic acid

Polylacticacid, poly (lactic acid) (PLA), according to the chiral of lactic acid, can be divided into levorotatory polylactic acid (PLA) L - and right hand (D - PLA), poly (lactic acid) (PLA) spin around blended polylactic acid (PLA) D, L - three chemical form[3], the main mechanical properties related to molecular weight. Due to the characteristics of thermoplastic, low toxicity, easy to process, good biocompatibility and adjustable degradation time, polylactic acid materials have been widely used in

vascular scaffolds, bone tissue repair and fixation materials, surgical sutures and other aspects[4]. Corresponding products applied to clinical has won the United States (Foodand Drug Administration, the FDA) and European regulators approved[5]. PLA can be degraded into lactic acid monomer to participate in the tricarboxylic acid cycle in vivo, and the final product is degraded to water and carbon dioxide[6]. The degradation rate of PLA mainly depends on the crystallinity, hydrophilicity, molecular side chain and molecular weight of the material itself, and the degradation behavior is affected by environmental temperature, PH value and humidity and other factors. Kelim et al.[7].coated a layer of poly (lactic acid) on the metal scaffold and conducted in vitro and in vivo experiments respectively to observe the degradation of PLA in the blood vessels at 6, 12, 24 and 36 months. The results showed that PLA degradation reached 20 at 6, 12 and 24 months.7%, 50.3% and 86.2%. It is estimated that at 36 months, the PLA coating on the stent can be degraded by hydrolysis [8].

2.2. Characteristics of PLA

J Ge et al. [9] mixed bioactive glass and polyl-l-lactic acid into tissue engineering scaffolds to study its degradation performance and biomineralization performance in simulated body fluid (SBF). The results showed that with the prolonged immersion time of the scaffold in SBF, the PH value of SBF decreased continuously and the overall quality presented a declining trend, with a weight loss rate of 3 within 1 week. The rate of weight loss within 8 weeks is 5.68%. The rate of weight loss within 16 weeks was 6.45%. LPLA acid degradation products can cause PH drop, which may lead to local tissue inflammation if not metabolized or excreted in vivo. The degradation time of poly (lactic acid) stents in arterial blood was different with the different implantation site. Scholars at Kyoto university [10] used polyethylenol-lprolactate (PGLA) stents to implant in the coronary arteries of dogs, and found that the degradation of the stents began at 1 to 2 weeks, and the degradation of the stents reached 50% at 8 weeks. Zidar et al. [8] implanted the stent made of l-poly (PLLA) into canine femoral artery, and found that the scaffold had been completely degraded after 18 months. Tamai et al. [11] observed the degradation behavior of PLLA stents after the implantation of human coronary arteries through intravascular ultrasound, and found no evidence of degradation of the stents within 6 months.

2.3. Silk Fibroin Materials

Silk fibroin materials have good biocompatibility, because it can be degraded and absorbed, and can be prepared into a variety of materials, so its application in tissue engineering scaffold materials has been widely concerned [12]. Chen mingjia et al. took silk fibroin as the matrix, sulfonated silk fibroin with sulfuric acid and introduced sulfonic acid group, so as to improve the anticoagulation of the material. The stents were prepared from fibroin/sulfonated fibroin by electrostatic spinning. The results of degradation experiments in vitro showed that the mass loss rate of electrospun fibroin/sulfonated fibroin materials after soaking in protease K and PBS solution for 24 days was 70, respectively.5% and 6.2%. In the animal experiment, the SD rat back was implanted subcutaneously. After 3 weeks, there was tissue adhesion in the material and part of the material was degraded. After 6 weeks, connective tissue grew into the material. Compared with pure silk fibroin, sulfonated silk fibroin has better histocompatibility and biodegradability [13]. Compared with PLA, the above intravascular degradable materials have been less studied, but these materials have their own characteristics and may be a supplement to PLA polymer scaffolds.

3. Degradable Magnesium Alloy

3.1. Degradation of Mg^{-2} alloys under different conditions

The reaction equation of corrosion of magnesium alloy in water is: $Mg+2H_2O = Mg(OH)_2+H_2$. In the presence of Cl^-, a reaction occurs: $Mg(OH)_2+2Cl^- = MgCl2+2OH^-$, which accelerates the corrosion of magnesium alloy and thus leads to accelerated degradation [14]. Magnesium is an essential element in the human body, which is involved in

the normal metabolic process of the human body. Magnesium alloy has high specific strength and specific stiffness, and good machinability. There have been many studies on scaffolds and their in vivo and in vitro degradation behavior [15]. Intravenous pyelography, ultrasound, blood and urine routine and stent-scanning electron microscopy images at different time points were used as monitoring indicators. The results showed that the biodegradable scaffold began to degrade at week 1 and was completely degraded at week 4.

There was no difference in indexes of hydronephrosis at 2 weeks after catheterization. At 3 to 4 weeks, hydronephrosis in the experimental group was less than that in the double-j tube control group. The blood and urine routine of the experimental group and the control group had no difference before and after catheterization. Scanning electron microscopy at different time points showed that the scaffold degraded in a predictable manner [16]. Histopathological examination of the specimen showed good biocompatibility. (Figure 1.) Different from the previous design, the bracket is made by textile method, which can ensure the same outer diameter and obtain thinner pipe wall and larger ratio of inner and outer diameter at the same time. Monitoring of the stent can be done by ultrasound imaging, if applied to children to avoid excessive X-ray radiation. The tensile strength and compressive strength of the support are both stronger than that of the ordinary double-j tube, which makes it not easy to bend or kink during implantation. Many side holes on the surface of the stent facilitate urine drainage.

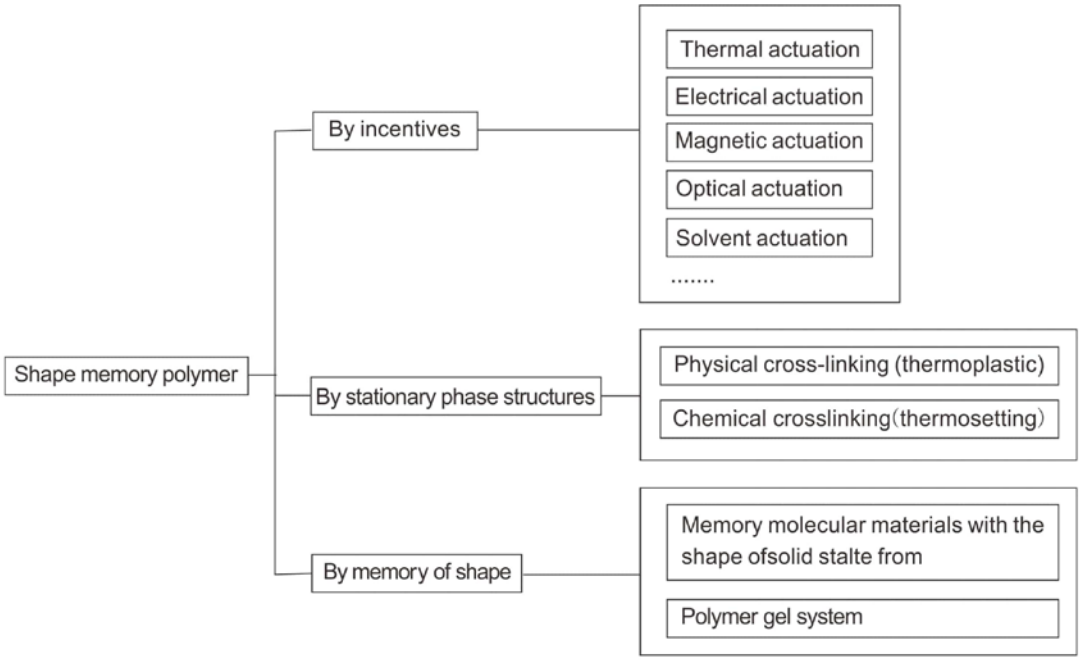

Figure 1. The classification of shape memory materials.

3.2. Development of Degradable Magnesium Alloy Stent Materials.

Yang ke et al. [17] studied the degradation behavior of AZ31 magnesium alloy in vivo and in vitro through different media and extraction conditions, and the results showed that the corrosion surface pits formed by the cast and heat treatment samples were deeper than the forged ones after 30 days, and the surface corrosion samples in the cast state were the most serious with the largest damage area. The rate calculated in Hank's solution is only 1/3 that of normal saline. They think it could be due to po43-4 and $HPO42^{-}$ forms phosphate with magnesium to reduce the degradation rate of magnesium alloys.

4. Conclusion

The greatest advantage of degradable ureteral stents is that they can be spontaneously degraded to avoid secondary invasive operation. For example, antibiotics or anti-tumor drugs can be mixed into the stents as a drug sustainer-release agent, which can provide a certain degree of precision treatment for urinary system diseases and thus have a broader prospect in clinical application. Biodegradable ureteral stents have achieved good results in some clinical studies, but their practicality still needs a large number of clinical trial evidence to support.

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